



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,245	02/18/2004	Rogier Receveur	P11377.00	3142
27581	7590	07/31/2006	EXAMINER	
MEDTRONIC, INC. 710 MEDTRONIC PARK MINNEAPOLIS, MN 55432-9924			SMITH, TERRI L	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 07/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/781,245

Applicant(s)

RECEVEUR ET AL.

Examiner

Terri L. Smith

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 February 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2-14-05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement (IDS) filed 14 February 2005 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the dates are not listed for any of the references cited on the IDS. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Drawings

2. The drawings are objected to under 37 CFR 1.83(a) because they fail to show the reference characters lead 100, thermistor 102, sheathing 104, wheatstone bridge arrangement 106 and lock-in amplifier 108 for FIG. 11 as described in the specification on page 14. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). The drawings are further objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 280 in FIG. 15. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office Action to avoid abandonment of the application. Any amended replacement drawing sheet should include

Art Unit: 3762

all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the Examiner, the Applicant will be notified and informed of any required corrective action in the next Office Action. The objection to the drawings will not be held in abeyance.

Specification

3. The disclosure is objected to because of the following informalities: On page 2, in the last line, it appears that word “be” should be the word “by” instead.

On page 5, in line 25, reference is made to FIGS. 2A-2B. The drawings do not contain these figures.

On page 9, in line 9, reference is made to FIG. 2B. The drawings do not contain this figure. The first part of the sentence in lines 22–25, “If the lead ... ,” is confusing. It appears that a word may be missing after the number “10” and the word “is” should be the word “it” instead.

On page 10, in line 19 reference character “54” has been used to designate both “imaging data” and “patient.”

On page 11, in lines 13–15 and 20, reference characters “56” and “58” have both been used to designate supplement patient data. And, reference character “58” has been used to designate both “supplement patient data” and “processor.”

On page 14, in lines 5–7, 9–10, and 12, the following reference characters are not shown in FIG. 11 as stated in the specification: lead 100, thermistor 102, sheathing 104, wheatstone bridge arrangement 106 and lock-in amplifier 108. In line 17, it appears that inserting the word “a” between the words “forms” and “portion” would add clarity to the sentence.

On page 16, in line 27, there appears to be a typographical error. It appears that the word “pint” should be “pin” instead.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: In claim 12, “an insulating ring disposed within the sleeve and hermetically sealed thereto” is not disclosed in the specification.

Appropriate correction is required.

Claim Objections

4. Claims 2 and 12 are objected to because of the following informalities: In claim 2, adding the word “a” between the words “is” and “pacemaker” would add clarity to the limitation.

5. In claim 12, it appears that its dependency should be from claim 11 rather than claim 10 as there is no surface area of the first membrane in claim 10. Examiner has examined the claim as depending from claim 11.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the Applicant regards as his invention.

7. Claims 1–12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 1, “housing” is inferentially included and vague. It cannot be determined if the housing is being positively recited or functionally recited. To positively claim the element, it is suggested to first positively recite the element. Otherwise, functional language such as “for” or “adapted to be” should be used. Additionally, “sensor comprising” is vague. It is unclear if the sensor or the implantable medical device is being described.

In claim 9, “means for hermetically sealing the means for sensing” is vague. In accordance with 37 C.F.R. 1.75, Applicant is required to specifically state what the means for hermetically sealing comprises by relating it to an or elements from the specification.

In claim 11, “an opening,” “a housing,” “an implantable medical device,” “an external medium,” and “a sensor” are all inferentially included and vague. It cannot be determined if the elements are being positively recited or functionally recited. Further, “is sensed” and “correlated” are incomplete. It is unclear where the sensor signal goes to in order for it to be correlated to a pressure.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

Art Unit: 3762

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 3–6 and 8–10 are rejected under 35 U.S.C. 102(b) as being anticipated by

Brehier, U.S. Patent 5,000,179.

10. Regarding claim 1, Brehier discloses an implantable device (Fig. 1) comprising a sleeve outer portion hermetically bonded (closed off sealingly) to a housing (4; column 3, lines 20); a thermal insulator disposed (10, insulation on the outer conductor of coaxial conductor 9) within a sleeve outer portion (4) (column 2, lines 55–56); a pin (7) spaced from the housing and at least partially disposed within a thermal insulator (10, insulation on the inner conductor of coaxial conductor 9); and a temperature sensor (16) disposed within a pin (7).

11. Brehier discloses an implantable device is a lead (3, probe) (claim 3); a pin includes an hollow interior (11) and the temperature sensor is disposed within the hollow interior (column 2, lines 55–57) (claim 4); a temperature sensor is in contact with an interior surface of a pin (column 2, lines 55–57) (claim 5); a thermal barrier (Fig. 2; element 18, housing) disposed within the hollow interior and isolating a temperature sensor (16) from an interior of the housing (claim 6); a sleeve inner portion (10, inside surface of the outer coaxial conductor insulation) disposed between a pin (3, probe) and a thermal insulator (10, outside surface of the inner coaxial conductor insulation) (claim 8); means for sensing a physical parameter (7); and means for hermetically sealing a means for sensing (claim 9) (column 2, lines 15–18 and 21–22); means for sensing is a temperature sensor (7) (claim 10).

12. Claims 11–12 are rejected under 35 U.S.C. 102(b) as being anticipated by Fraley et al., U.S. Patent Application Publication 2002/0165588.

Art Unit: 3762

13. Regarding claim 11, Fraley et al. disclose a feedthrough assembly (Figure 9 (A–C)) comprising: a sleeve disposed within an opening through a housing of an implantable medical device and hermetically sealed to a housing (71, capacitor; paragraph [0066], lines 14–15); an insulating ring disposed within a sleeve and hermetically sealed thereto (76, 77); a pin disposed within and hermetically sealed to the insulating ring (75, paragraph [0066], lines 14–15), a pin including a hollow, fluid filled interior (Figure 9, the cavity surrounding 74 and 75 is the hollow fluid filled interior), a first membrane exposed to an external medium (74), and a second membrane (72, polyimide disk) operably coupled with a sensor (71, capacitor) disposed within a housing, wherein a physical parameter of a second membrane is sensed by a sensor and correlated to a pressure within an external medium (paragraph [0066], lines 3–8, wherein the leak testable assembly is correlated to pressure). For claim 12, Fraley et al. disclose a surface area of a first membrane (74) is smaller than a surface area of a second membrane (72) (Figure 9A).

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

Art Unit: 3762

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 1, 3 and 6–7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fraley et al., U.S. Patent Application Publication 2002/0165588.

17. Regarding claim 1, Fraley et al. disclose an implantable device including a feedthrough (Figure 9) comprising a sleeve outer portion hermetically bonded to a housing (71, capacitor; paragraph [0066], lines 14–15); a thermal insulator disposed within a sleeve outer portion (76); a pin (75) spaced from a housing and at least partially disposed within a thermal insulator (Figure 9). Fraley et al. disclose a sensor (74) disposed within a pin, but not a temperature sensor.

However, it is well known in the art to use sensors as temperature sensors to measure, monitor and calibrate temperatures within implantable devices to alert a person when there is a potential problem and to ensure efficient and optimal function and operation of a device. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Fraley et al. to include a temperature sensor to provide an optimally performing implantable device.

18. With respect to claim 6, Fraley et al. disclose a thermal barrier (76, insulator) disposed within a hollow interior and isolating a sensing electrode (74) from an interior of a housing (claim 6) (Figure 9A), but Fraley et al. do not disclose a temperature sensor. Fraley et al. disclose a sensor (74), but not a temperature sensor. However, it is well known in the art to use sensors as temperature sensors to measure, monitor and calibrate temperatures within implantable devices to alert a person when there is a potential problem and to ensure efficient

Art Unit: 3762

and optimal function and operation of a device. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Fraley et al. to include a temperature sensor to provide an optimally performing implantable device.

19. Fraley et al. disclose an implantable device is a lead (claim 3) (14); a thermal barrier extends beyond a hollow interior of a pin and into an interior of the housing (claim 7) (Figure 9A).

20. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brehier or Fraley et al., as applied to claim 1 above, and further in view of Miesel et al., U.S. Patent 6,144,866.

21. Brehier and Fraley et al. disclose the essential features of the claimed invention as discussed above, except for an implantable device is a pacemaker cardioverter defibrillator. However, Miesel et al. disclose an implantable device is a pacemaker cardioverter defibrillator (Figs. 1 and 2B; column 6, lines 54–55; column 19, line 51) to allow more accurate measurement of physiological parameters in a patient's heart by coupling to a temperature sensor. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the inventions of Brehier or Fraley et al. to include an implantable device is a pacemaker cardioverter defibrillator to provide an effective way to sense physiological parameters in a patient's heart.

Conclusion

22. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Terri L. Smith whose telephone number is 571-272-7146. The Examiner can normally be reached on Monday - Friday, between 7:30 a.m. - 4:00 p.m..


If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



TLS
July 13, 2006

13 July 2006



GEORGE R. EVANISKO
PRIMARY EXAMINER
7/17/6